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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,460	12/29/2005	Etienne Pouteau	3712036.00697	6141
29157	7590	05/19/2010		
K&L Gates LLP P.O. Box 1135 CHICAGO, IL 60690			EXAMINER LAU, JONATHAN S	
			ART UNIT 1623	PAPER NUMBER
			NOTIFICATION DATE 05/19/2010	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chicago.patents@klgates.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/562,460	<b>Applicant(s)</b> POUTEAU ET AL.	
	<b>Examiner</b> Jonathan S. Lau	<b>Art Unit</b> 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8 Apr 2010 has been entered.

This Office Action is responsive to Applicant's Amendment and Remarks, filed 8 Apr 2010, in which claims 1 and 5 are amended to change the scope and breadth of the claim, claims 3 and 6-12 are amended to use the language of claims 1 and 5, and new claim 13 is added.

This application is the national stage entry of PCT/EP04/07092, filed 30 Jun 2004; and claims benefit of foreign priority document EP 0301486.7, filed 30 Jun 2003. This foreign priority document is in English.

Claims 1 and 3-13 are pending and examined on the merits herein.

### ***Rejections Withdrawn***

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Applicant's Amendment, filed 8 Apr 2010, with respect to claims 1 and 3-12 rejected under 35 U.S.C. 103(a) as being unpatentable over Takada et al. (US Patent Application Publication 2003/0181401, filed 3 Feb 2003, of record) in view of Schumann (Eur. J. Nutr., 2002, 41 (Suppl 1), pl/17-I/25, of record) and in view of Spiller (CRC Handbook of Dietary Fiber in Human Nutrition, 2001, 3<sup>rd</sup> Ed, p373-400, of record) has been fully considered and is persuasive, as amended claims 1 and 5 require administering a product comprising a lactulose, a protein source in an amount from about 21 to about 40% by weight of the product, a lipid source in an amount from about 5% to about 40% of the total energy of the product, and a carbohydrate source in an amount that is less than 10% by weight of the product and and Takada et al. in view of Schumann and in view of Spiller teaches a composition comprising a saccharide containing galactose such as lactulose, 5-30% by weight amino acids, 40% by weight or less lipids, 40-80% by weight saccharide, and 0.05 to 1% by weight artificial sweetener.

This rejection has been **withdrawn**.

The following are new grounds of rejection.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 3-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Upon further review of the language of claim 1, it is unclear what amount of the claimed product is administered and therefore it is unclear what elements are necessary to practice the claimed invention. Claims 3, 4 and 7-10 depend from claim 1 and incorporate all limitations therein. Claims 3 and 7-10 recite limitations of the amount of lactulose in said composition but do not recite what amount is administered. The specification suggests the acetogenic fiber lactulose is the agent for treating and/or improving insulin resistance, however Schumann (Eur. J. Nutr., 2002, 41 (Suppl 1), p1/17-1/25, of record) discloses lactulose is also used as a food additive for its flavor enhancing properties (page 1/21, right column, paragraph 2). Claim 1 does not require administering an effective amount of said product. Therefore one of ordinary skill in the art would not be readily apprised of the metes and bounds of the invention as recited in the claims.

Claims 1 and 5 recite “protein source”, “lipid source” and “carbohydrate source” (emphasis added). Claims 3, 4 and 7-10 depend from claim 1 and incorporate all limitations therein. Claim 6, 11 and 12 depend from claim 5 and incorporate all limitations therein. The terms “protein source”, “lipid source” and “carbohydrate source” render the claims indefinite because it is unclear what is the scope of these terms. The specification provides only non-limiting examples of proteins as a protein source (page 7, lines 5-10), fats as the lipid source (page 7, lines 10-15), and the inclusion or exclusion of monosaccharides as the carbohydrate source (page 7, lines 15-25). One of skill in the art would understand that via metabolic pathways raw materials such as glucose are used to make amino acids and proteins or used to make lipids, therefore it

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is unclear if said carbohydrate is a "protein source", a "lipid source" or a "carbohydrate source". Therefore one of ordinary skill in the art would not be readily apprised of the metes and bounds of the invention as recited in the claims.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Genovese et al. (Diab. Nutr. Metab. 1992, 5, p295-297, cited in PTO-892) in view of Florent et al. (J. Clin. Invest. 1985, 75, p608-613, cited in PTO-892).

Genovese et al. teaches the administration of lactulose to non-insulin dependent diabetic patients (page 295, abstract). Genovese et al. teaches the administration

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results in a reduction of blood glucose after challenging with an oral glucose tolerance test (OGTT) with no significant difference in serum insulin concentration (page 296, right column, paragraphs 1-2). Genovese et al. teaches the effect is more pronounced from 90 to 180 min after the glucose load (page 296, right column, paragraphs 3) and suggests the fermentation of lactulose in the colon has some influence on blood glucose metabolism (page 296, right column, paragraphs 4-5).

Genovese et al. does not specifically teach the method reduces insulin resistance or administering lactulose between 3 and 7 hours before a meal (instant claim 13).

Florent et al. is drawn to the colonic metabolism of lactulose in man such as transit time of ingested lactulose to the colon (page 612, paragraph spanning bottom of left column and top of right column). Florent et al. teaches, for example, a time to lactose peak concentration at the ileum of 172 to 210 minutes (page 610, table III at top of right column).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine Genovese et al. in view of Florent et al. It would have been obvious to one of ordinary skill in the art to combine the teaching of Genovese et al. to give the method of treating insulin resistance by reducing insulin resistance because Genovese et al. teaches a reduction of blood glucose with no significant difference in serum insulin concentration in non-insulin dependent diabetic patients, or patients having insulin resistance, suggesting a reduction of resistance to the same level of insulin. One of ordinary skill in the art would have been motivated to combine

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Genovese et al. in view of Florent et al. to administer the lactulose 172 to 210 minutes before a meal because Genovese et al. teaches the effect of the lactulose is more pronounced 90 to 180 min after the glucose load and suggests it is the fermentation of lactulose in the colon that has some influence on blood glucose metabolism, and Florent et al. teaches the transit time of ingested lactulose to the colon.

### ***Conclusion***

The application is not currently in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jonathan Lau  
Patent Examiner  
Art Unit 1623

/Shaojia Anna Jiang/  
Supervisory Patent Examiner  
Art Unit 1623